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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,492	01/23/2004	Fredric R. Bloom	0942.5490002/RWE/FRC	4921

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WASHINGTON, DC 20005

EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/762,492

Applicant(s)

BLOOM ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-107 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-14 and 77-97 are drawn *E. coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294 and a composition comprising *E. coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, classified in class 424, subclass 241.1.
 - II. Claims 15-26, 36-44 and 62-76 are drawn to a method of cloning comprising an obtaining step; a transformation step; a selection step and a culturing step, a method of transforming *E. coli* comprising an obtaining step, an incubation step and a culturing step and a kit for cloning, classified in class 435, subclass 252.8.
 - III. Claims 27-35 are drawn to a method of producing a protein or peptide, classified in class 435, subclass 69.1.
 - IV. Claims 45-52 and 55-61 are drawn to a method of producing *E. coli* for cloning, comprising obtaining *E. coli* and an introduction step, classified in class 435, subclass 173.8.
 - V. Claims 98-107 are drawn to a method for selecting for *E. coli* that contain plasmid, classified in class 435, subclass 4.
2. The inventions are distinct, each from the other because of the following reasons:

(I) Inventions II-V are related as distinct methods. The methods are distinct as claimed because they have different methods with different method steps; different functions and the effects have different final outcomes. Group V is drawn to a method for

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selecting for *E. coli* that contain plasmid. The method of Group II has a different function, i.e., a method of cloning comprising an obtaining step; a transformation step; a selection step and a culturing step. Groups III and V are distinct from each other and from the methods of the other groups. For instance, only the method of Group III produces a protein or peptide which is distinct from the results of any other group. Each Group produces different effects and different functions when compared to the other Groups. For these reasons the inventions of Groups II-V are patently distinct.

Furthermore, the distinct methods require separate and distinct searches. The inventions of Groups II-V have acquired a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the each method is not coextensive. Group V requires a search drawn to a method for selecting for *E. coli* that contain plasmid, which is not required for the search of Groups II or III. For instance, the prior art that teaches a method of producing a protein or peptide would not necessarily be associated with a method and kit for cloning comprising an obtaining step; a transformation step; a selection step and a culturing step. Likewise, the search for Group II would require a text search drawn cloning, and such a search would not necessarily encompass a search for the method Group III. Therefore, said searches would not necessarily include a search for the other inventions.

Moreover, even if the method of cloning comprising an obtaining step; a transformation step; a selection step and a culturing step were known, the method for selecting for *E. coli* that contain plasmid may be novel and unobvious in view of the

preamble. As such, it would be burdensome to search the inventions of Groups II-V together.

Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the *E. coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294 can be produced by methods other than the recited method of production. For instance, the *E. coli* can be produced by introducing vectors that do not contain genetic mutations, but contain multiple copies of growth increasing genes. Therefore the product as claimed can be made by another and materially different process, thus the inventions are distinct.

Furthermore, searching the inventions of Group I and Group V would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. *E. coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294 requires a different search than the search for a method of production. For instance, group I only requires *E. coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294 while Group V further requires that the *E. coli* have a mutation introduced. Such a search is not required to identify the product of Group I. Furthermore, product of Group I may be known even if a

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method of Group V is novel. In addition, the technical literature search for the product of Group I and the method of Group V are not coextensive.

3. Because these inventions are distinct for the reasons given above, and have acquired a separate status in the art as shown by their different classification, the search required for each group is not required for the other groups since each group requires a different non-patent literature search due to each group comprising different method steps, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is

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subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, A. Mark Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
September 26, 2006